Attorney Docket No. 329241

OIPE IAP82
SEP 14 2006
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

GOLDENBERG

Application No.: 10/680,734

Filed: 10/8/2003

For: ANTIBODY THERAPY

Examiner: LYNN ANNE BRISTOL

Art Unit: 1643

INFORMATION DISCLOSURE STATEMENT
(37 C.F.R. §§ 1.97(b)(3) and 1.98)

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Examiner is requested to consider the references noted on the enclosed Form PTO/SB/08A (Substitute for form 1449A/PTO) during examination of the above-identified application. These references are submitted for the Examiner's consideration and are submitted pursuant to the duty of disclosure under 37 C.F.R. § 1.56. In submitting these references, no representation is made or implied that the references are or are not material to the examination of the application. The Examiner is encouraged to make his or her own determination of materiality.

Should any additional fees be deemed necessary, such fees may be charged to Deposit Account No. 06-0029.

09/15/2006 RMEBRAHT 00000061 10680734
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Should the examiner have any questions concerning the relevance of any reference cited in this disclosure, please contact the undersigned attorney.

Dated: September 8, 2006

Respectfully submitted,

Richard A. Nakashima
Registration No. 42,023
Customer No. 35657

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SEP 14 2006
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	10/680,734; Confirmation 5299
Filing Date	10/8/2003
First Named Inventor	Goldenberg
Art Unit	1643
Examiner Name	Lynn Anne Bristol
Attorney Docket Number	329241

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	Document Number Number - Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US-4,818,709	4/4/1989	Primus et al.	
	2	US- 5,081,235	1/14/1992	Shively et al.	
	3	US- 5,530,101	6/25/1996	Queen et al.	
	4	US- 5,874,540	2/23/1999	Hansen et al.	
	5	US- 4,970,071	11/13/1990	McMichael	
	6	US- 6,077,499	6/20/2000	Griffiths et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] - Number[4] - Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	7	WO 92/01059	1/23/1992	Adair		
	8	EP 0 323 805 A3	7/12/1989	Buchegger		
	9	EP 0 323 806 A1	7/12/1989	Hardman		
	10	EP 0 239 400 A2	9/30/1987	Winter		
	11	WO 92/11018	7/9/1992	Queen		
	12	JP 02154696 A	6/14/1990	Hardman		
	13	JP 5-502587	5/13/1993	Adair		
	14	WO 91/01990	2/21/1991	Shively		
	15	WO 95/15769	6/15/1995	Hansen		

Examiner Signature		Date Considered	

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Sheet 3 of 4

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Filing Date	10/8/2003
First Named Inventor	Goldenberg
Art Unit	1643
Examiner Name	Bristol
Attorney Docket Number	329241

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	Document Number Number - Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-			
		US-			
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	16	EP 0 620 276 A1	10/19/1994	Adair		
	17	WO 96/01126	1/18/1996	Hansen		
	18	WO 96/08506	3/21/1996	Leung		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

Complete if Known	
Application Number	10/680,734; Confirmation 5299
Filing Date	10/8/2003
First Named Inventor	Goldenberg
Art Unit	1643
Examiner Name	Bristol
Attorney Docket Number	329241

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	19	PRIMUS, F. JAMES, et al. "Immunological Heterogeneity of Carcinoembryonic Antigen: Antigenic Determinants on Carcinoembryonic Antigen Distinguished by Monoclonal Antibodies" Cancer Research 43, 686-692, February 1983 pgs. 686-692	
	20	HANSEN, HANS J. "Characterization of Second-Generation Monoclonal Antibodies Against Carcinoembryonic Antigen" Cancer, 71(11):3478-85, Jun. 1993, pgs. 3478-3485	
	21	LOSMAN, MICHELE J., "Mimicry of a Carcinoembryonic Antigen Epitope by a Rat Monoclonal Anti-Idiotype Antibody," Int. J. Cancer: 56, 580-584 (1994)	
	22	SHARKEY, ROBERT M., et al., "Clinical Evaluation of Tumor Targeting with a High-Affinity, Anticarcinoembryonic-Antigen-Specific, Murine Monoclonal Antibody, MN-14" Cancer 71(6):2082-2096 (1993)	
	23	RIECHMANN, Lutz, et al., "Reshaping Human Antibodies for Therapy" Nature Vol. 332 24 March 1988 pgs. 323-327	
	24	QUEEN, CARY, et al., "A Humanized Antibody that binds to the interleukin 2 receptor" Proc. Natl. Acad. Sci. USA Vol. 86, pp. 10029-10033, December 1989	
	25	BLUMENTAL, ROSALYN D., et al. "Targeted Therapy of Athymic Mice Bearing GW-39 Human Colonic Cancer Micrometastases with 131I-labeled Monoclonal Antibodies" Cancer Research 52, 6036-6044, November 1, 1992	
	26	VERHOEYEN, et al., "Reshaping Human Antibodies: Grafting an Antilysozyme Activity" Science, Vol 239, 9/29/1987, pgs. 1534-1536	
	27	SHARKEY, ROBERT M., "Comparison of Tumor Targeting in Nude Mice by Murine Monoclonal Antibodies Directed against Different Human Colorectal Cancer Antigens" Cancer Research (Suppl.) 50, 828s-834s, February 1, 1990	
	28	MUYLDERMANS, S., et al., "Sequence and structure of VH domain from naturally ocurring camel heavy chain immunoglobulins lacking light chains" Protein Engineering Vol. 7 No. 9 pp. 1129-1135, 1994	
	29	STEIN, RHOMA, et al., "Combining Radioimmunotherapy and Cemotherapy for Treatment of Medullary Thyroid Carcinoma" CANCER Volume 94, No. 1, January 1, 2002, pp. 51-61	

Examiner Signature		Date Considered	

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Sheet 4 of 4

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Filing Date	10/8/2003
First Named Inventor	Goldenberg
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Examiner Name	Lynn Anne Bristol
Attorney Docket Number	329241

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	30	JUWEID, MALIK E., "Phase I/II Trial of 131I-MN-14 F(ab)2 Anti-Carcinoembryonic Antigen Monoclonal Antibody inn the Treatment of Patents with Metastatic Medullary Thyroid Carcinoma" Cacer Vol 85, No. 8 April 15, 1999, pp. 1828-1842	
	31	JUWEID, MALIK E. et al., "Radioimmunotherapy of Patients with Small-Volume Tumors Using Iodine-131-Labeled Anti-CEA Monoclonal Antibody NP-4 F(ab')2" The Journal of Nuclear Medicine, Vol 37, No. 9, September 1996, pp. 1504-1510	
	32	SHARKEY, Robert M., et al., "Evaluation of a Complementarity-Determining Region-Grafted (Humanized) Anti-Carcinoembryonic Antigen Monoclonal Antibody in Preclinical and Clinical Studies" Cancer Research Suppl. 155, December 1, 198, pp 5935s-5945s	
	33	JUWEID, MALIK, et al., "Radioimmunotherapy of Medullary Thyroid Cancer with Iodine-131-Labeled Anti-CEA Antibodies" The Journal of Nuclear Medicine, Vol 37, No. 6, June 1996 pp. 905-911	
	34	STEIN, RHONA, et al., "A Humanized monoclonal antibody to carcinoembryonic antigen, labetuzumab, inhibits tumor growth and sensitizes human medullary thyroid cancer xenografts to dacarbazine cemotherapy" Mol. Cancer Ther 2004;3(12), December 2004, pp. 1559-1564	

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	7

Application Number	10/680,734; confirmation 5299
Filing Date	10/8/2003
First Named Inventor	Goldenberg
Art Unit	1643
Examiner Name	Bristol, Lynn Anne
Attorney Docket Number	329241

ENCLOSURES ***(check all that apply)***

- ☐ Fee Transmittal Form
- ☒ Fee Attached
- ☐ Amendment / Reply
- ☐ After Final
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
- ☐ Reply to Missing Parts under 37 CFR1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:

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12 foreign patent references; and 16 non-patent references

Remarks

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm	FAEGRE & BENSON LLP		
Signature			
Printed Name	Richard A. Nakashima		
Date	9/8/06	Reg. No.	42,023

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Typed or printed name	Laura S. Mellblom	Date	9-11-06

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